DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 31 2004

Re: Dermagraft
Docket No.: 03E-0033

The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,963,489, filed by Advanced Tissue Sciences, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Dermagraft, the medical device claimed by the patent.

The total length of the regulatory review period for Dermagraft is 4,050 days. Of this time, 3,650 days occurred during the testing phase and 400 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: August 29, 1990.

   The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on September 2, 1992. FDA records confirm that one IDE for this medical device did become effective on September 2, 1992. However, FDA records also indicate that another IDE for this medical device was determined substantially complete for clinical studies to have begun on August 29, 1990, which represents the IDE effective date. Although this IDE was for a different indication, it is material to the approval of Dermagraft. FDA considers all investigational exemptions for a particular product to be material to the approval of the product regardless of any difference between the indications studied and those ultimately approved.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: August 25, 2000.

03E-0033

LET 4

The applicant claims August 24, 2000, as the date the premarket approval application (PMA) Dermagraft] (PMA P00036) was initially submitted. However, FDA records indicate that PMA P00036 was submitted on August 25, 2000.

3. The date the application was approved: September 28, 2001.

FDA has verified the applicant's claim that PMA P00036 was approved on September 28, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Francis D. Cerrito, Esq.
Pennie & Edmond, L.L.P.
1155 Avenue of the Americas
New York, NY 10036